



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,797	07/26/2002	Achim Gopferich	02592	1932

7590 09/04/2008
KENTON R. MULLINS
STOUT, UXA, BUYAN & MULLINS, LLP
4 VENTURE
SUITE 300
IRVINE, CA 92618

EXAMINER

SILVERMAN, ERIC E

ART UNIT	PAPER NUMBER
----------	--------------

1618

MAIL DATE	DELIVERY MODE
-----------	---------------

09/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/019,797	Applicant(s) GOPFERICH ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5 and 9-44 is/are pending in the application.
- 4a) Of the above claim(s) 12,13 and 16-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5,9-11 and 33-44 is/are rejected.
- 7) ☒ Claim(s) 34,35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/5/2008 has been entered. Pursuant to this submission, claims 1-3, 5 and 9-44 are pending, claims 12, 13, 16-32 are withdrawn, and claims 1-3, 5, 9-11, 14, 15 and 33-44 are treated on the merits in this action.

Specification

The specification is objected to for the following technical inaccuracy. On page 30, section b) Synthesis of NH₂-PEG-PLA, the specification states that synthesis was conducted in accordance with two references. The USPTO has obtained these references, and neither of them teaches the synthesis of NH₂-PEG-PLA. The references instead teach the polymerization of lactide with tin alkanoate catalysts. Appropriate correction should be made, and care should be taken to avoid the introduction of any new matter.

Claim Objections

Claims 34 and 35 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s)

Art Unit: 1618

in proper dependent form, or rewrite the claim(s) in independent form. Claim 34 allows the hydrophilic polymer or the hydrophobic polymer to be, *inter alia*, "a branched polymer". Claim 1, upon which claim 34 depends, requires "a linear block copolymer". A branched polymer is not linear, and thus claim 34 does not limit the scope of claim 1. Claim 35 lists several alternative species for the hydrophobic polymer a). This list includes species that are not present in the list of permissible hydrophobic polymer a) identities in claim 1. As claim 35 depends on claim 1, it fails to further limit the parent claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2 and 3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 allows that the second functional end group is "for binding of a surface-modifying substance d)" which is understood to read on both instances where said surface-modifying substance d) is bound and those instances where it could be, but has not yet actually been bound. In the former case, where surface-modifying substance d) is bound to second functional endgroup c2), c2) would by necessity have at least one bond to the linear block copolymer (of which is it a part) and at least one bond to the substance d). In this case, it cannot be a "primary amino group", as a primary amino group would have one bond to the linear block copolymer and two bonds to hydrogen.

Art Unit: 1618

In the same manner, the hydrophilic polymer b) could not be PEG-NH₂ (where NH₂ is c2)), because the NH₂ cannot have a bond to the substance d). Some clarification of this point would be helpful. Also, with regard to claim 3, poly(ethylene glycol) amine need not be PEG-NH₂; PEG-NH-d) is also poly(ethylene glycol) amine, wherein the amine is further bound to d), as per claim 1.

For the purposes of examination, these claims are interpreted to read on cases where c2) is a primary amine *before* the attachment of group d); that is, in cases where group d) is present, the claims are understood to read on polymers that where c2) would be a primary amine, or b) would be PEG-NH₂ if group d) were removed.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 5, 6-10, 14, 15, 33-44 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,365,173 to Domb et al. (hereafter "the 173 patent").

1. Claim interpretation issues

The claims are replete with language requiring that particular functional end groups are "for binding of a surface-modifying substance," wherein such binding may be "either directly or by way of an at least bifunctional molecule," and similar recitations. These limitations are all preceded by terms like "for binding", and as such they are understood to be recitations of future intended uses of the claimed linear block copolymer. As such, in applying prior art to the claims, it is not required that a "surface-

Art Unit: 1618

modifying substance" actually be bound, nor is it required that there be "an at least bifunctional molecule". The claims only require that a surface modifying substance *could* be bound either directly or by way of some hypothetical at least bifunctional molecule. Thus, descriptions of the at least one bifunctional molecule, for example in claims 39 and 40, are not taken as structural limitations to the claim because there is no requirement that the bifunctional molecule actually be present. However, it is also understood that art showing the claimed linear block-copolymer when the linear block copolymer is bound to a surface-modifying substance either directly or by way of a bifunctional molecule will also read on the claimed invention.

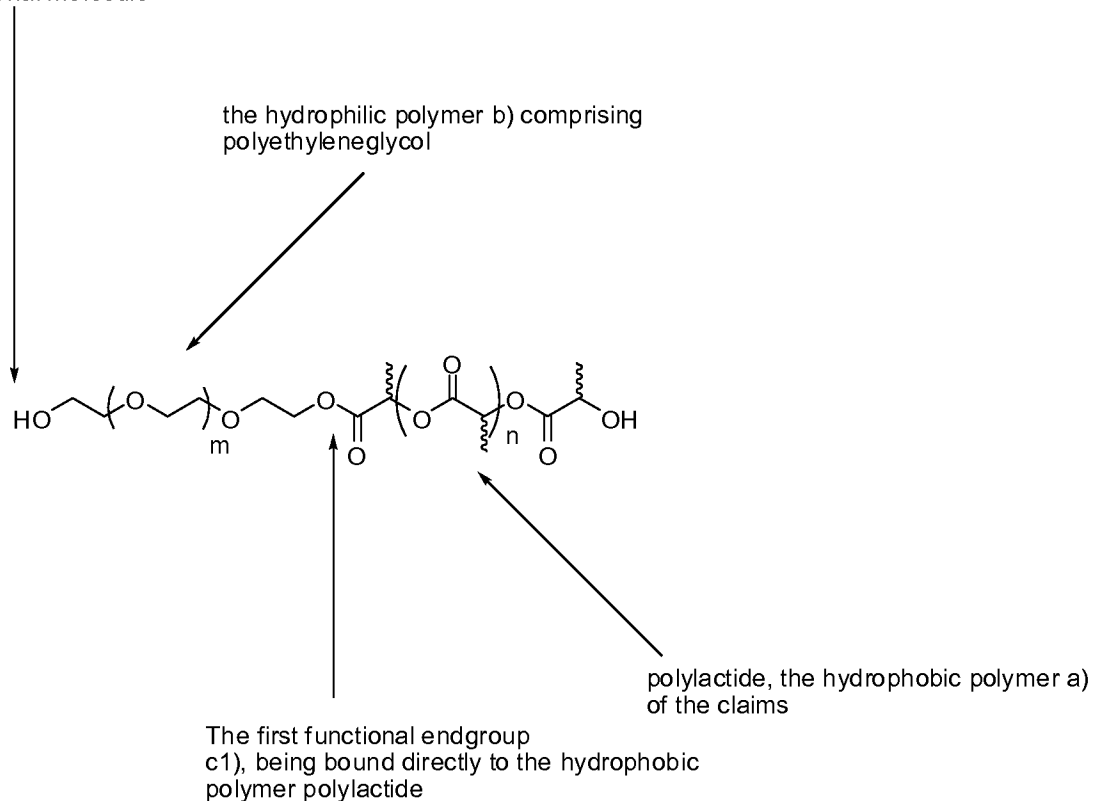
2. Explanation of the prior art and reason for the holding of anticipation

The 173 patent teaches A-B block copolymers such as poly(L-lactide)-b-poly(ethyleneglycol) (L-PLA-b-PEG) and the corresponding D-PLA-b-PEG (made from D-lactide instead of L-lactide). Col. 6 and Example 11. The structure of this polymer is drawn below with annotations in order to explain why it contains each component, c2)-b)-c1)-a), as required by instant claim 1. Note that in this drawing, three PEG and three lactide groups are drawn, instead of the usual notation where one of each comonomer is depicted, in order to facilitate the explanation. Note also that, based on the methods of making described in the patent, the polymer is not end-capped. As such, the PEG component is drawn with its natural -OH terminal group. Finally, note that the lactide monomers are drawn without specifying the stereochemistry, although the reference specifically makes isotactic polymers containing either all D- or all L- lactide. Because the claims do not address stereochemistry, the tacticity of the polymer is not relevant in

Art Unit: 1618

the discussion of how the art applies to the claims, and so the specific stereochemistry it is omitted.

the second functional end group c2)
being capable of binding a surface-modifying
substance either directly or by way of an at
least bifunctional molecule



It is noted that c2) in the above polymer is an -OH group, which the artisan recognizes is capable of acting as a nucleophile, or of being derivatized to act as an electrophile, and is thus capable of undergoing chemical reactions that could bind a surface-modifying substance either directly or by way of an at least bifunctional molecule. Also note that the two free

The molecular weights are not disclosed directly, but col. 6 indicates the degrees of polymerization of the lactide and glycolide blocks, and the indicated degrees of

Art Unit: 1618

polymerization are within the scope of the claimed molecular weights. In example 11, the polymers are formed into self-assembled supra-structures with a bioactive agent. This is understood to read on "[a] shaped body" within the scope of instant claim 14. Further, the materials are observable by atomic force microscopy (AFM), and thus are "three-dimensional bod[ies]" within the scope of instant claim 15.

Claims 1-3, 5, 11, 14, 15 and 33-44 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,254,890 to Hirose et al. (hereafter "the 890 patent").

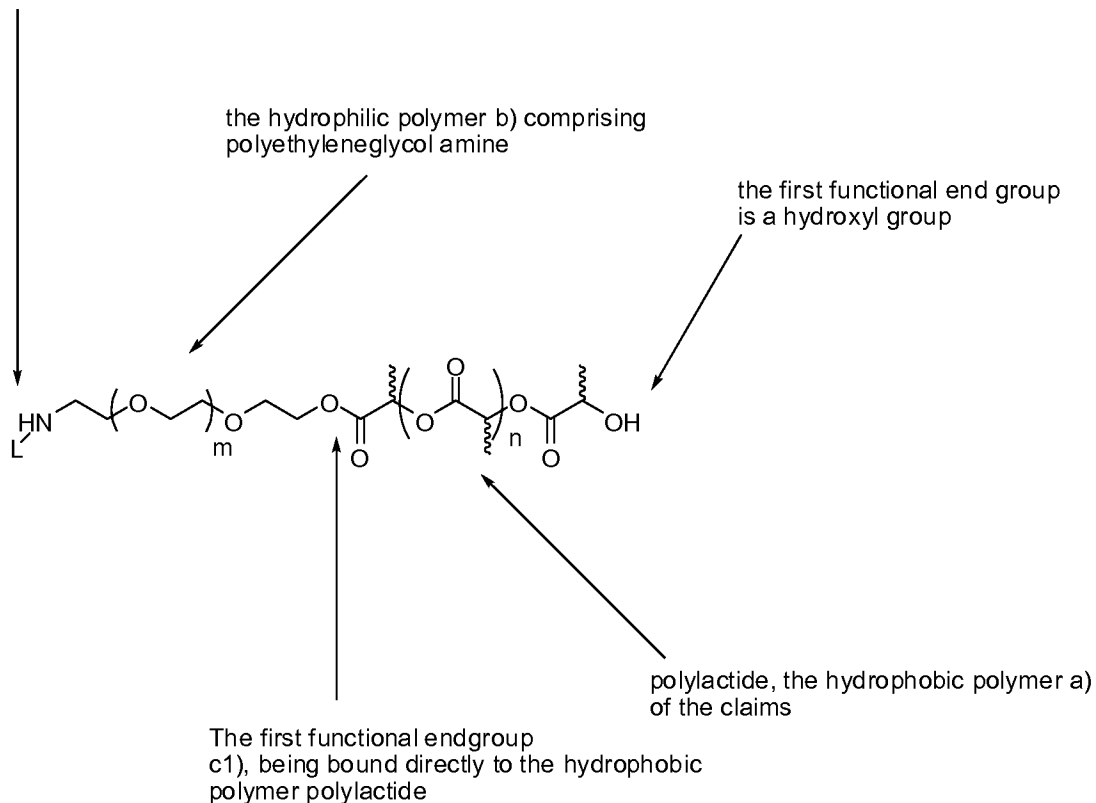
Issues of claim interpretation have been discussed above.

The 890 patent, at example 4, teaches the use of PEG-PLA, which is the copolymer of instant claims. The structure of PEG-PLA was discussed above, as was the reason why it reads on instant claims.

The 890 patent also discloses functionalizing the PEG using N-hydroxysuccinimidyl esters so that amine groups from desirable ligands can be reacted with the copolymer. Such reaction would lead to a having a end hydroxyl group and an amino PEG. The "desirable ligand" of the 890 patent is understood to fall within the scope of substance d) of instant claims. The diagram below explains how the disclosed copolymer reads on the instant claims.

Art Unit: 1618

the second functional end group c2)
bound to substance d) (here "L"), wherein
c2) would be a primary amine if d) were
not present



The 890 patent also teaches making particles of the polymers described therein, which particles are within the scope of the shaped body of instant claim 14 and the three-dimensional body of instant claim 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1618

Claims 1-3, 5, 9-11, 14, 15 and 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over the 890 patent, as applied to claims 1-3, 5, 11, 14, 15 and 33-44 above, in view of the 173 patent.

What is lacking from the 890 patent is the molecular weights of the PLA-PEG polymers. The 173 patent teaches appropriate molecular weights of such polymers for use in drug delivery.

It would have been prima facie obvious to a person of ordinary skill in the art at the time of the invention to use the molecular weights taught by the 173 patent. The motivation stems from the 173 patent teaching appropriate molecular weights for drug delivery, and that both references use the polymers for drug delivery.

Conclusion

No claims are allowed. Claims 34 and 35 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric E Silverman/
Examiner, Art Unit 1618

Application/Control Number: 10/019,797
Art Unit: 1618

Page 10